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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,730	09/01/2000	Marvin Whiteley	UIZ-038	5801

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LAHIVE & COCKFIELD
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BOSTON, MA 02109

EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/653,730

Applicant(s)

WHITELEY ET AL.

Examiner

Ja-Na A Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-26 and 75 is/are pending in the application.
- 4a) Of the above claim(s) 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-26 is/are rejected.
- 7) ☒ Claim(s) 3,4,7,9,17,21 and 24-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed March 19, 2003 has been entered. The examiner acknowledges the amendment to the specification. Claims 2 and 27-74 have been cancelled. Claims 1, 3, 4, 7, 9, 17, 21, 24, 25 and 26 have been amended. Claims 1, 3-26 are under consideration.

Election/Restrictions

2. Newly submitted claim 75 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claim is drawn to a method of identifying a modulator of quorum sensing signaling comprising SEQ ID NO: 1-36. The inventions are distinct, each from the other because the methods rely upon the nucleotide sequences selected from SEQ ID NO: 1-36 which are distinct physically and structurally; and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each group comprises separate and distinct nucleotide sequences that do not share a substantial structural feature disclosed as being essential to the utility of the invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 75 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawal of Rejections

3. The following rejections have been withdrawn:
- a) the enablement rejection claims 1-26 under 35 U.S.C. 112, first paragraph;
 - and
 - b) the rejection of claims 1-26 under 35 U.S.C. 112, second paragraph.

Claim Objections

4. Claims 3, 7,9, 17, 21 24, 25 and 26 are objected to because of the following informalities: The claims depend upon non-elected claim 75. Appropriate correction is required.

Response to Arguments

5. Applicant's arguments filed March 19, 2003 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. The rejection of claims 1, 3-7, 9-10, 13-15 and 17-26 under 35 U.S.C. 102(b) as being anticipated by Pearson et al., (J. of Bacterio. 1997. 179(18): 5756-5767) is maintained for reasons already of record. The rejection was on the grounds that Pearson et al., teach a method for identifying a modulator of quorum sensing signaling in bacteria, comprising the claimed steps.

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Applicants assert that Pearson et al., do not teach or suggest the method for identifying a modulator because Pearson et al., utilizes a *P. aeruginosa lasI rhII* double-mutant that cannot endogenously produce a quorum sensing signal molecule.

However it is examiner's position that the claims only require a cell which is capable of endogenously synthesizing a quorum sensing signal, therefore, the cell does not have to actually be able to synthesize a quorum sensing signal. Furthermore, applicant points to one mutant that Pearson et al., teach. However Pearson et al., teach several other cells which would be capable of endogenously producing a quorum sensing signal. Thus the fact that one cell would not be capable of synthesis does not teach away from the other cells that would be capable of said synthesis. Therefore applicants' argument to that one example is not persuasive, when the prior art teaches other capable examples.

7. The rejection of claims 8, 11-12 and 16 under 35 U.S.C. 103(a) as being unpatentable over Pearson et al., (J. of Bacterio. 1997. 179(18): 5756-5767) in view of Passador et al., (Science, 1993. 260:1127-1130) is maintained for reasons already of record. The rejection was on the grounds that it would have been prima facie obvious at the time of applicants invention to modify the method for identifying a modulator of quorum sensing signaling in bacteria comprising the recited steps as taught by Pearson et al., to include a second cell that produces the quorum sensing signal molecule, instead of adding the molecule to the cell.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one would have a reasonable expectation of success in using a second cell to produce the molecule since Passador et al., teach that the expression of *P. aeruginosa* virulence genes requires cell-to-cell communication whereby one cell produces the molecule and the other cell can respond to the production of the molecule.

Applicants argument that Pearson et al., in view of Passador et al., do not teach or suggest a cell which is capable of endogenously synthesizing a quorum sensing signal because Pearson et al., utilizes a *P. aeruginosa lasI rhII* double-mutant which cannot endogenously produce a quorum sensing signal molecule, is not persuasive for the reasons previously stated.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

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reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Therefore, no more than routine skill would have been required to incorporate a second cell which is a wild type *P. aeruginosa* cell that ^{expresses} ~~express~~ one of the virulence factors, using cells constructed in a similar manner as the cells of Pearson et al., which allow detection of a change to identify a compound as a modulator of quorum sensing signaling in bacteria. Therefore, applicants' arguments are not persuasive.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines 
May 28, 2003


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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